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(54) **Expandable blood clot filter.**

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Description

Background of the Invention

Field of the Invention

The invention relates generally to devices for filtering emboli from blood circulating within a blood vessel, and more particularly, to devices for vena cava filters inserted by the femoral vein approach.

Description of the Prior Art

The presence of emboli within the body's circulatory system presents a serious health hazard which can often become life endangering, such as when an embolus travels into the lungs (pulmonary embolus). Most commonly, these emboli are formed in the lower extremities, especially in patients suffering from phlebitis, patients recovering from surgery, and also non-ambulatory patients who must endure long periods of muscular inactivity. Blood clots or emboli that are formed in the lower extremities, such as the legs, must travel through the inferior vena cava in order to reach the heart, where the emboli are then pumped into the lungs becoming pulmonary embolisms.

One technique used in the prior art which served to prevent emboli from traveling into the lungs and becoming pulmonary embolisms involves the ligation of the vena cava in order to block the passage of any emboli. This technique also prevents the flow of blood through the vena cava, thus requiring the development of collateral circulation to provide passageways for satisfactory blood circulation to the heart. Because of the many disadvantages inherent in performing the major surgery required for the ligation of the vena cava, other methods have been developed.

One of the methods, disclosed in U.S. Patent No. 3,834,394 to Hunter et al., involves a detachable balloon attached to the distal end of a catheter. The balloon and catheter are inserted by making a surgical incision in one of the veins of the neck and then using the catheter to position the balloon within the inferior vena cava. Once detached, the balloon occludes the inferior vena cava entirely, thus preventing all blood flow. While this method avoids major surgery, it still requires a surgical incision to be performed. Further, since this method also requires total occlusion of the inferior vena cava, the patient is very weak until collateral circulation eventually develops around the balloon. Hopefully, by this time, the reason for the existence of an embolism problem has past. Since this method requires the inferior vena cava to be entirely occluded, it is only used in extreme cases.

Another method for preventing pulmonary embolisms, but which does not require total occlusion of the inferior vena cava, involves implanting a filter device constructed similar to the frame of an umbrella as a permanent implant within the inferior vena cava. Such a device is disclosed in U.S. Patent No. 3,540,431 to Mobin-Uddin. While the Mobin-Uddin device avoids total occlusion, its design does partially occlude the inferior vena cava. In addition, the Mobin-Uddin device does not avoid the disadvantages of the other previous methods in that it still requires a small incision to be made in the jugular vein and passage of the filter through the heart in order to be positioned within the inferior vena cava. This device, therefore, suffers the inherent disadvantages associated with a jugular vein approach, partial occlusion of the inferior vena cava and surgery.

Experience with devices similar to those disclosed above has demonstrated the desirability of a device which would not only serve to trap the migration of emboli but which would also not obstruct caval blood flow at any time, thus eliminating the requirement of collateral circulation. Ideally, the device should be constructed in order that it may be implanted by a femoral approach, as opposed to a more difficult jugular vein approach. Additionally, the device should not create additional emboli and should be capable of relatively secure anchoring at the desired body location within the blood vessel.

U.S. Patent No. 3,952,747 to Kimmel discloses a blood vessel filter and filter insertion instrument which overcomes some of the disadvantages of the previous references. The Kimmel reference discloses a method which allows the filter to be inserted by a femoral approach, although this method still requires surgery in order to effect insertion. The device disclosed in the Kimmel reference uses a filter comprised of a plurality of wire legs in a generally conical array and joined at their convergent ends to an apical hub. The wire legs each include a plurality of bends intermediate along their length which decrease the solids by-pass capability of the filter without substantially occluding the blood vessel. Thus, the Kimmel reference discloses a blood clot filter which avoids the collateral circulation requirement inherent in the previous devices and the disadvantages associated with a jugular or other neck vein approach.

The filter disclosed in the Kimmel reference, however, still suffers certain disadvantages. One disadvantage, which is inherent in the conical design of the filter, is that the anchoring means must be placed at the divergent ends of the wire legs in order to securely anchor the device within the blood vessel. As a result, the divergent ends of the wire legs must be substantially collapsed and sheathed in order for the filter to be inserted within the blood vessel, and a fairly complicated means must be used to unsheath the filter for implantation within the blood vessel. Thus, the filter disclosed in the Kimmel reference cannot be inserted within a blood vessel using normal percutaneous catheterization techniques. In order to use the filter disclosed in the Kimmel reference, it is necessary to perform a venotomy or incision of the blood vessel, for its insertion therein. Further, once insertion within the blood vessel is effected, a syringe type ejection means is required in order to be able to unsheath the filter for implantation.

Driller et al. (Medical and Biological Engineer-

ing, Vol. 14, No. 6, November 1976, pages 629—635) describes an inferior-vena-cava filter consisting of a number of barbed strands of spring-tempered stainless steel, joined together at a hub. This filter is adapted to be introduced into the vein by a catheter using a wire guide. Although the open conical network of the filter functions as a sieve to trap emboli whilst permitting blood flow, tests on dogs resulted in thrombus formation on the hub.

Other references which disclose devices providing partial or total occlusion of a blood vessel in order to prevent emboli from reaching the lungs are U.S.P. 3,334,629 to Cohn and U.S.P. 3,795,246 to Sturgeon.

The device disclosed in the present invention overcomes the disadvantages associated with the prior art by employing a non-occlusive filter which is designed to be inserted using normal percutaneous catheterization techniques combined with a femoral approach. Thus, the need for surgery is totally obviated as well as the need for a syringe, such as disclosed in the Kimmel reference. A further improvement offered by the filter of the present invention and not found in any of the previous references involves its wire mesh design. The wire mesh design permits the filter to become firmly attached not only at the initial anchor points at the ends of the wires, but also along portions of wire lengths which directly abut the intimal wall of the blood vessel. The contact of the filter against the vessel wall along these portions permits endothelization and fibrotic encasement of the filter to the intimal wall surface to an extent not previously attainable using previous designs.

Accordingly, it is an object of the present invention to provide a blood clot filter which may be implanted using normal percutaneous catheter techniques combined with a femoral approach.

It is a further object of the present invention to provide a blood clot filter which is designed to be placed within the inferior vena cava, well below the renal veins.

It is a yet further object of the present invention to provide a blood clot filter which will not obstruct blood flow within the blood vessel at any time.

It is a still further object of the present invention to provide a blood clot filter which will not create additional emboli after implantation.

An additional object of the present invention to provide a blood clot filter which is capable of being securely anchored within the blood vessel.

These and other objects and advantages of the present invention will become more apparent in the following figures and detailed description.

Summary of the Invention

The present invention provides a blood clot filter for positioning within the fluid passageway of a blood vessel in a human body. The blood clot filter comprises a shape memory wire capable of assuming two functional positions. In its first position the wire is substantially straightened to permit retention of the filter in the lumen of an angiography catheter. In its second position the wire is substantially contracted along its length in order to form a curly wire mesh. The potential energy which is stored in the wire in its straightened position is sufficient to force the wire in its contracted position into urging contact with the intimal wall of a blood vessel at a multiplicity of contact points. The contact of the wire of the filter with the intimal wall of the blood vessel aids in the anchoring of the filter at a predetermined body location within the blood vessel and also encourages endothelization and fibrotic encasement at the contact points. The wire has a sufficiently small diameter to prevent substantial occlusion of the blood vessel when the filter is implanted. The blood clot filter further comprises anchoring means on said wire for anchoring said filter at a determined body location within said blood vessel, said anchoring means including a plurality of sharp projections for penetrating into said intimal wall of said blood vessel.

Brief Description of the Drawings

FIG. 1 is a fragmentary elevation view of the blood clot filter of the present invention in a totally straightened position.

FIG. 2 is an elevation view of the blood clot filter of the present invention in a partially straightened position.

FIG. 3A is an enlarged detail view of one of the two forward anchoring means in the blood clot filter of the present invention.

FIG. 3B is an enlarged detail view of one of the two rearward anchoring means in the blood clot filter of the present invention.

FIG. 4 is an enlarged fragmentary perspective view which illustrates how the wire guide is attached and detached from the blood clot filter in order to effect implantation of the blood clot filter within a body blood vessel, such as the inferior vena cava.

FIG. 5 is a fragmentary view of the wire guide handle.

FIG. 6 is a fragmentary view, partially in section, of the cartridge catheter.

FIG. 7 is a fragmentary view of the catheter sheath.

FIG. 8 is a fragmentary view of the dilator.

FIGS. 9—16 are diagrammatic views illustrating various steps in performing a catheterization of the inferior vena cava using the clot filter assembly of the present invention to implant the blood clot filter therein.

FIG. 17 is a perspective view of a portion of the inferior vena cava and having a section removed to show the configuration of the blood clot filter in its implanted and anchored position within the inferior vena cava.

Description of the Preferred Embodiment

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be

used to describe the same. However, this embodiment is described by way of example only.

Referring now to the drawings, FIGS. 1 and 2 show the blood clot filter of the clot filter assembly of the present invention generally designated at 10. Filter 10 is shown in a totally straightened position in FIG. 1 with its wire strands slightly spaced apart so that the construction of filter 10 may be more clearly seen. FIG. 2 shows filter 10 in a partially straightened but also somewhat curled position. It should be understood that filter 10 would normally assume the shape of a curly wire mesh unless external forces are employed to straighten the wire strands. It is also to be understood that filter 10 would be provided to the physician in a prepackaged assembly additionally including a cartridge catheter and a wire guide handle, both of which will be more fully described herein.

Filter 10 includes six strands of stainless steel wire which are connected to each other in the following manner. Innermost strands 11 and 12 are mutually attached at both ends by crimps 13 and 14. Innermost strands 11 and 12 are approximately 25 centimeters in length and are made from .007 inch (.018 cm) diameter coil wire. Outermost strands 15 and 16 are located oppositely of innermost strands 11 and 12 and are each connected thereto at both ends by wire strands 17 and 18. Outermost strands 15 and 16 are approximately 38 centimeters in length and are made from .007 inch (.018 cm) diameter coil wire. Wire strand 17 serves to connect outermost strands 15 and 16 with innermost strands 11 and 12 at the distal end of filter 10. In a similar manner, wire strand 18 connects outermost strands 15 and 16 with innermost strands 11 and 12 at the proximal end of filter 10. Wire strand 17 is secured to outermost strands 15 and 16 by crimps 21 and 22, respectively and to innermost strands 11 and 12 by crimp 13. In a similar fashion, wire strand 18 is secured to outermost strands 15 and 16 by crimps 19 and 20, respectively, and to innermost strands 11 and 12 by crimp 14. Wire strands 17 and 18 are approximately 10 centimeters in length and are made from .010 inch (.025 cm) diameter stainless steel coil wire. Crimps 19—22 are made from 3 mm of 22 GTW cannula while crimps 13 and 14 are made from 3 mm lengths of 19.5 GTW cannula. Innermost strands 11 and 12, and outermost strands 15 and 16 are made from a shape memory material, such as spring temper stainless steel.

During manufacture, wire strands 11, 12, 15 and 16 are curled in different directions and wadded together to form a curly wire mesh. Because of their shaped memory construction, innermost strands 11 and 12 and outermost strands 15 and 16 may be straightened out at their ends substantially as shown in FIG. 1 for loading into the lumen of a Teflon angiography catheter cartridge. It may be noted that once loaded within the catheter, the spring bias inherent within the wire strands will cause some curling thereof. Further curling is, of course, restrained by the intimal wall of the catheter cartridge. Thus, it is the spring bias inherent in the shape memory construction which allows filter 10 to expand radially outward as innermost wire strands 11 and 12 and outermost wire strands 15 and 16 contract along their lengths upon insertion in a body blood vessel, as will be more fully explained herein.

Means for anchoring filter 10 within a body blood vessel, such as the inferior vena cava, is generally designated at 24 and 25, the details of their construction being more clearly understood by reference FIGS. 2, 3A and 3B. It is to be understood that anchoring means 24 is located at the rearward end of both wire strands 15 and 16, while anchoring means 25 is located at the forward end of both wire strands 15 and 16. Anchoring means 24 differs from anchoring means 25 due to the presence of a barb 30 whose purpose will become fully apparent hereinafter. In the preferred embodiment, the anchoring means 24 and 25 at the ends of outermost wire strand 15 are longitudinally staggered from the corresponding anchoring means 24 and 25 at the ends of outermost wire strand 16. This permits the easy loading of filter 10 within the lumen of a catheter cartridge such as will be more fully described herein.

Referring particularly to FIGS. 2 and 3B, the details of construction of the rearward anchoring means 24 will now be described. It is to be understood that while only the rearward anchoring means 24 at the end of outermost wire strand 15 is described, the rearward anchoring means 24 at the end of outermost wire strand 16 is of a similar construction. It is seen that rearward anchoring means 24 includes a length 26 of outermost wire strand 15 located at the rearward end thereof. Length 26 is approximately one centimeter in length and has a sharp end point 27 which is meant to enter the wall of a blood vessel in the manner shown in FIG. 3B. In order to prevent too deep penetration of anchoring means 24 through the blood vessel, a loop 28 of wire formed from wire strand 18 is positioned adjacent length 26. Loop 28 extends approximately 7 mm along length 26, crimp 19 serving to secure the end of loop 28.

It is to be understood that there are two forward anchoring means 25 at the forward end of filter 10. As previously mentioned, forward anchoring means 25 is of a similar construction to anchoring means 24 except that a barb 30 is received over the end length of wire corresponding to length 26 of anchoring means 24. The purpose of barb 30 is to provide a more secure anchor at the down stream end of filter 10 and thereby ensure long term patency of the filter. Barbs 30 are secured to the forward ends of the outermost wire strands 15 and 16 by soldering. FIG. 3A shows the construction of one of the two barbs 30 in detail. Each of the barbs 30 have a lancet bevelled portion 31 which faces outwards of filter 10 and a hooked portion 32 at the inwards facing end. Hooked portion 32 serves to prevent barb 30 from becoming dislodged from the body blood vessel

once penetration thereof has been made. Each of the barbs 30 is constructed from 6 mm of .028 inch (.071 cm) diameter cannula.

Referring again to FIG. 2, wire strand 18 is shown having a zig-zag 34 therein which is located approximately 7 mm rearward of crimp 14. The purpose of zig-zag 34 will become more clear by reference to FIG. 4 which shows zig-zag 34 and the distal portion 35 of wire guide handle 36 immediately adjacent thereto. As seen in FIG. 4, zig-zag 34 permits the attachment of wire guide handle 36 for remote-controlled movement of filter 10. Wire guide handle 36 is made from a length of .018 inch (.046 cm) diameter mandrel wire. As seen in FIG. 5, the proximal end of wire guide handle 36 forms a handle portion 37 which facilitates rotation of wire guide handle 36, while the distal portion 35 consists of a helically formed length of .010 inch (.025 cm) wire coil. Distal portion 35 is made by merely extending or stretching in a longitudinal direction the distal portion 35 of wire guide handle 36 which has a conventionally known helical construction. The innermost end 37a of distal portion 35 is then silver soldered for additional strength. The stretched distal portion 35 of wire guide handle 36 may then be screwed on to wire strand 18 for attachment thereto at zig-zag 34 by clockwise rotation of wire guide handle 36. In order to control depth of body insertion of wire guide handle 36, sutures such as seen at 38 may be tied thereto at measured locations.

It is easily perceived that once distal portion 35 of wire guide handle 36 has been attached to wire strand 18 at zig-zag 34, it is possible to move wire strand 18 and thus also filter 10 longitudinally by merely pushing or pulling on wire guide handle 36. Also, in order to disattach wire guide handle 36 from filter 10 it is only necessary to unscrew distal portion 35 of wire guide handle 36 from zig-zag 34 of wire strand 18 by counter-clockwise rotation. Zig-zag 34 is formed by double bending wire strand 18 so that zig-zag 34 extends substantially perpendicular to the length of filter 10.

FIGS. 6—8 depict the cartridge catheter 40, sheets 50, and dilator 60 of the clot filter assembly of the present invention. FIG. 6 shows cartridge catheter 40 including a tubular portion 41 which is approximately 40 centimeters in length and is made from 8.0 French size Teflon tubing having an outer diameter of .105 inch (.267 cm) and an inner diameter of .073 inch (.185 cm). Tubular portion 41 is connected to a rear assembly which includes coupling member 43, side port fitting 44 and cap 45. Fitting 44 is externally threaded at both ends for attachment to coupling member 43 and cap 45. Coupling member 43 has an internally threaded portion along its forward end which permits coupling to the distal end of sheath 50 in a manner which will be described more fully herein. Cap 45 includes a latex washer 47 which permits cartridge catheter 40 to be firmly held in place over wire guide handle 36, the purpose of which will become apparent later. This is accomplished by tightening cap 45 onto side port fitting 44 so as to compress latex washer 47 against wire guide handle 36.

Referring now to FIG. 7, sheath 50 is shown to include a tubular portion 51 which is fixedly attached to connector cap 52. Connector cap 52 includes a male coupling means which consists of a collar 53 which serves to permit coupling between sheath 50 and either cartridge catheter 40 or dilator 60. Sheath 50 has a lumen 54 therein which extends along the entire length of sheath 50. Tubular portion 51 is approximately 37.5 cm in length and is made from 8.5 French size sheathing having an outer diameter of .133" (0.338 cm) and an inner diameter of .113" (0.287 cm).

Referring now to FIG. 8, dilator 60 is shown including a tubular portion 61 which is fixedly attached at its proximal end to connector cap 62. Connector cap 62 is of similar construction to connector cap 52 of sheath 50, and no further explanation of its construction is necessary. Tubular portion 61 has a dilator tip 63 which extends approximately .8 cm rearwards from the distal end of dilator 60 and serves to facilitate the introduction of sheath 50 within a body blood vessel in performing a catheterization. Tubular portion 61 is approximately 41 cm in length and is made from 8.0 French size Teflon tubing. Tubular portion 61 has an outer diameter of .105" (.267 cm) and an inner diameter of .073" (0.185 cm), except along the length of dilator tip 63 which is, of course, gradually smaller as it approaches the distal end of dilator 60.

In order to use the clot filter assembly of the present invention filter 10, wire guide handle 36 and cartridge catheter 40 are provided to the physician preassembled as follows. Filter 10 and wire guide handle 36 are attached in the manner previously described and filter 10 is loaded within the lumen of cartridge catheter 40. Loading filter 10 inside cartridge catheter 40 is accomplished by first straightening the innermost strands 11 and 12 and outermost strands 15 and 16 of filter 10. Of course, filter 10 will contract slightly within the lumen of cartridge catheter 40 as it is loaded therein, however, the lumen of cartridge catheter 40 is sufficiently small to force wire strands 11, 12, 15 and 16 of filter 10 to retain a substantially straight orientation.

FIGS. 9—16 illustrate the steps involved in using the clot filter assembly of the subject invention. In order to place and anchor filter 10 within the inferior vena cava 65, a percutaneous catheterization is performed in the normal manner, the initial insertion being effected with a hollow thin wall needle and wire guide using a femoral approach. The needle and wire guide may be of any conventionally known and suitable type, it being understood that no further description of their construction is necessary for those skilled in the art. Then, with tubular portion 61 of dilator 60 inserted within the lumen of sheath 50 and connector cap 62 threadingly coupled over collar 53 of sheath 50, the sheath and dilator combination is inserted within the femoral vein 66. Once sheath 50 and dilator 60 are properly in-

serted, the dilator and initial wire guide are removed. Cartridge catheter 40, along with filter 10 and attached wire guide handle 36, is then inserted within the lumen of sheath 50 until coupling member 43 is threadably coupled over collar 53 of sheath 50. As depicted in FIG. 9, sheath 50 and cartridge catheter 40 are thereafter passed under fluoroscopic control to a desired position approximately 1 cm above the renal veins 67 and 68. Cartridge catheter 40 should be filled with radiopaque medium by injection through side port fitting 44, this being done for visualization purposes. Cap 45 is then unscrewed until wire guide handle 36 is loosened for longitudinal movement within lumen of cartridge catheter 40 (FIG. 10). Thereupon, as depicted in FIG. 11, and with wire guide handle 36 being held in place, cartridge catheter 40 is pulled rearwardly approximately 4 cm, thereby exposing the two barbs 30. In order to seat the barbs within the inferior vena cava wall, cartridge catheter 40 and wire guide handle 36 are sharply advanced (FIG. 12) as a unit 1 to 2 cm. It has been found that 2 or 3 such jab-like movements will assure firm seating.

Referring now to FIG. 13, after the barbs 30 are firmly secured, cartridge catheter 40 is withdrawn approximately 8 cm while wire guide handle 36 is held firmly in place. This places the distal end of cartridge catheter 40 well below renal veins 67 and 68 and in a position from which the remaining portions of filter 10 may be fed into a position within the inferior vena cava below the renal veins.

As seen in FIG. 14, the next step requires wire guide handle 36 to be advanced as far as it will go, i.e. up to the first right angle bend of handle portion 37, while firmly holding cartridge catheter 40 in place. This movement feeds the remaining portions of filter 10 into the inferior vena cava 65. Once filter 10 is fully positioned within the inferior vena cava, the rearward anchoring means 24 (FIG. 15) are seated by sharply pulling back cartridge catheter 40 and wire guide handle 36 as a unit, approximately 1—2 cm.

It is to be appreciated that due to the potential energy stored within wire strands 11, 12, 15 and 16 in their substantially straightened position within cartridge catheter 40, filter 10 contracts longitudinally and at the same time expands radially to encompass the entire blood passageway of the inferior vena cava 65. Further radial expansion is, of course, restricted by the intimal wall of the inferior vena cava.

After it has been determined that filter 10 is successfully implanted within the inferior vena cava, it is necessary to separate wire guide handle 36 from filter 10. As depicted in FIG. 16, this is accomplished by turning wire guide handle 36 approximately 20 revolutions to unscrew it from filter 10. Separation can usually be identified by fluoroscopy. If the stretched distal portion 35 catches on any of the wire strands of filter 10, it is only necessary to continue counter-clockwise rotation as wire guide handle 36 is withdrawn in order to free it.

FIG. 17 shows filter 10 in its longitudinally contracted and radially expanded position within the inferior vena cava of a human body. It is to be noted that in this position filter 10 is in the shape of a curly wire mesh with spaces therethrough no larger than 3—4 mm. Also, due to the relatively small diameters of the wire strands, filter 10 occupies only a minimal portion of the cross-sectional area of the blood vessel passageway. Thus, filter 10 does not substantially occlude the blood vessel passageway. Also, barbs 30 extend into the intimal wall of the inferior vena cava in such fashion so as to firmly anchor filter 10, thereby ensuring long term patency.

In addition to the anchoring points at barbs 30, FIG. 17 also shows filter 10 in urging contact with the intimal wall 70 of the inferior vena cava 65 at innumerable other points along the lengths of various portions of the wire strands of filter 10. Initially, these points of urging contact do not provide sufficient anchoring to ensure patency of filter 10, thus requiring the anchoring means provided by barbs 30. However, after several weeks endothelization and fibrotic encasement occurs at the points where the wire mesh of filter 10 abuts the intimal wall of the inferior vena cava, and the likelihood of permanent patency is thereafter greatly increased.

While the foregoing description applies to the insertion of filter 10 in the inferior vena cava of a human body using a femoral approach, it is to be understood that the device of the subject invention may be used with different techniques such as a jugular approach. The device of the subject invention may also be used to effect the filtering of emboli or other obstructions from blood vessels other than the inferior vena cava. Of course, the size and shapes of various elements described herein would have to be varied in order to accomplish such other techniques or uses, but such variations as may be necessary would be well within the skill of those knowledgeable in the art.

Claims

1. A blood clot filter (10) for positioning within the fluid passageway of a blood vessel in a human body, comprising:

a shape memory wire contractible from a first position wherein said wire is substantially straightened to permit insertion of the filter within the lumen of an angiography catheter (40), and wherein the wire stores sufficient potential energy to force said wire into a second position in which it is in urging contact with the intimal wall of said blood vessel at a multiplicity of contact points, thereby aiding the anchoring of said filter at a desired body location within said blood vessel and encouraging endothelization and fibrotic encasement at said contact points, said wire having a sufficiently small diameter to prevent substantial occlusion of said blood vessel when said filter is implanted therein; and

anchoring means (24, 25) on said wire for anchoring said filter at a determined body loca-

tion within said blood vessel, said anchoring means including a plurality of sharp projections (27, 30) for penetrating into said intimal wall of said blood vessel,

characterised in that in said second position the wire is contracted along its length to form a curly wire mesh.

2. A blood clot filter according to claim 1, characterised by introduction means (34) integral with said wire for facilitating the introduction of said wire into said blood vessel through the lumen of said catheter (40).

3. A blood clot filter according to claim 1 or claim 2, characterised in that said projections (27, 30) are positioned at opposite ends of said filter (10).

4. A blood clot filter according to claim 3, characterised in that said anchoring means (24, 25) includes four projections (27, 30), two each positioned at opposite ends of said filter, said projections longitudinally staggered at each end to facilitate loading of said filter within said catheter.

5. A blood clot filter according to any preceding claim, characterised in that said wire includes a plurality of strands (11, 12, 15, 16).

6. A blood clot filter according to claim 5, characterised in that said wire includes four or more strands.

7. A blood clot filter according to claim 6, characterised in that each strand (11, 12, 15, 16) is connected at both ends to at least one other strand (17, 18) and a plurality of said strands are connected at at least one intermediate point (13, 14) along their lengths.

8. A blood clot filter according to claim 7, characterised in that each of the two said projections at the forward end of said filter include a barb (30) sharpened at both ends.

9. A blood clot filter according to claim 8, characterised in that said barbs (30) have a length which is less than 1 cm.

10. A blood clot filter according to claim 2, characterised in that said introduction means is a zig-zag (34) in said wire, said zig-zag providing a surface substantially perpendicular to the length of said wire when said wire is in its first position, thereby permitting said filter (10) to be urged longitudinally through the lumen of said catheter (40) for positioning in said blood vessel.

11. A blood clot filter according to claim 9, characterised in that said wire is made of tempered stainless steel.

12. A blood clot filter according to claim 10, characterised in that said wire has a diameter which is less than .015 inches (.038 cm).

13. An assembly for performing a catheterization of a blood vessel in a human body in order to filter emboli from blood circulating through said blood vessel, said assembly comprising:

a catheter (40) sized to be received within the passageway of said blood vessel and inserted therein over a wire guide (36);

a blood clot filter (10); and

said wire guide (36) having a diameter sized to permit said wire guide to be received through the lumen of said catheter (40), said wire guide including means for urging said filter out of an end of said catheter and into a determined body location within the passageway of said blood vessel,

characterised in that said blood clot filter (10) is a filter according to any preceding claim.

14. An assembly according to claim 13, further characterised by a dilator (60) including a tubular portion (61) having a lumen therethrough, said tubular portion having a tip portion (63) of narrowing cross-section for dilating said blood vessel in order to permit the subsequent insertion of said catheter (40).

15. An assembly according to claim 14, further characterised by:

a catheter sheath (50) having a lumen (54) therethrough and sized to be received over said tubular portion (61) of said dilator (60), said catheter sheath lumen being sized to receive said catheter (40).

16. An assembly according to claim 13, characterised in that said wire guide (36) is helically formed, and said urging means is a stretched helical portion (35) of said wire guide located at one end thereof and which is stretched relative to the remaining portion of said wire guide.

Patentansprüche

1. Filter (10) für Blutgerinnsel zur Positionierung im Fluiddurchgang eines Blutgefäßes in einem menschlichen Körper, der aufweist:

einen Draht mit Formmemory-Verhalten, der aus einer ersten Position, in der der Draht im wesentlichen geradegestreckt ist, um den Filter in den Hohlraum eines Angiographie-Katheters (40) einzuführen, sich zusammenziehen kann, wobei der Draht ausreichend potentielle Energie speichert, um den Draht in eine zweite Position zu zwingen, in der er in Andrückkontakt mit der Innenwand des Blutgefäßes in einer Vielzahl von Kontaktstellen ist, wodurch die Verankerung des Filters an einer gewünschten Körperstelle in dem Blutgefäß unterstützt und eine Endothelisation und ein fibrotischer Einschluß an diesen Kontaktstellen angeregt wird, und wobei der Draht einen ausreichend kleinen Durchmesser hat, um eine nennenswerte Okklusion des Blutgefässes zu verhindern, wenn der Filter in diesem implantiert ist, und

Verankerungseinrichtung (24, 25) an dem Draht zur Verankerung des Filters an einer vorbestimmten Körperstelle im Blutgefäß, wobei die Verankerungseinrichtung eine Vielzahl von scharfen Vorsprüngen (27, 30) enthält, die in die Innenwand des Blutgefäßes eindringen, dadurch gekennzeichnet, daß in der zweiten Position der Draht längs seiner Längserstreckung zusammengezogen wird, um ein gekräuseltes Drahtgeflecht zu bilden.

2. Filter für Blutgerinnsel nach Anspruch 1, gekennzeichnet durch eine Einführungseinrichtung (34), die einteilig mit dem Draht ausgelegt

ist, um das Einführen des Drahtes in das Blutgefäß durch den hohlen Innenraum des Katheters (40) zu erleichtern.

3. Filter für Blutgerinnsel nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Vorsprünge (27, 30) an gegenüberliegenden Enden des Filters (10) angeordnet sind.

4. Filter für Blutgerinnsel nach Anspruch 3, dadurch gekennzeichnet, daß die Verankerungseinrichtungen (24, 25) vier Vorsprünge (27, 30) enthalten, von denen zwei jeweils an den gegenüberliegenden Enden des Filters angeordnet und diese Vorsprünge in Längsrichtung an jedem Ende versetzt angeordnet sind, um das Einbringen des Filters in den Katheter zu erleichtern.

5. Filter für Blutgerinnsel nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, daß der Draht eine Mehrzahl von Strängen (11, 12, 15, 16) umfaßt.

6. Filter für Blutgerinnsel nach Anspruch 5, dadurch gekennzeichnet, daß der Draht vier oder mehr Stränge umfaßt.

7. Filter für Blutgerinnsel nach Anspruch 6, dadurch gekennzeichnet, daß jeder Strang (11, 12, 15, 16) an beiden Enden mit wenigstens einem anderen Strang (17, 18) verbunden ist und daß eine Mehrzahl von Strängen an wenigstens einem Zwischenpunkt (13, 14) längs ihrer Längserstreckung verbunden sind.

8. Filter für Blutgerinnsel nach Anspruch 6, dadurch gekennzeichnet, daß jede der beiden Vorsprünge am vorderen Ende des Filters einen Widerhaken (30) enthalten, der an beiden Enden scharf ist.

9. Filter für Blutgerinnsel nach Anspruch 8, dadurch gekennzeichnet, daß die Widerhaken (30) eine Länge haben, die kleiner als 1 cm ist.

10. Filter für Blutgerinnsel nach Anspruch 2, dadurch gekennzeichnet, daß die Einführungseinrichtung ein Zickzackteil (34) im Draht ist, und daß das Zickzackteil eine Fläche bildet, die im wesentlichen senkrecht zur Längserstreckung des Drahtes ist, wenn der Draht sich in seiner ersten Position befindet, wodurch ermöglicht wird, daß der Filter (10) in Längsrichtung durch den Innenraum des Katheters zur Positionierung im Blutgefäß gedrückt wird.

11. Filter für Blutgerinnsel nach Anspruch 9, dadurch gekennzeichnet, daß der Draht aus wärmebehandeltem rostfreiem Stahl hergestellt ist.

12. Filter für Blutgerinnsel nach Anspruch 10, dadurch gekennzeichnet, daß der Draht einen Durchmesser hat, der kleiner als 0,015 inch (0,038 cm) ist.

13. Anordnung zum Durchführen einer Katheterisierung eines Blutgefäßes in einem menschlichen Körper, um Emboli aus dem durch das Blutgefäß zirkulierenden Blut auszufiltern, wobei die Anordnung aufweist:

einen Katheter (40), der derart bemessen ist, daß er in dem Durchgang des Blutgefäßes aufgenommen werden kann und über einen Führungsdraht (36) in dasselbe einführbar ist,

einen Filter (10) für Blutgerinnsel, und

der Führungsdraht (36) einen so großen Durchmesser hat, daß ermöglicht wird, daß die Drahtführung in dem Innenraum des Katheters (40) aufgenommen ist, und wobei die Drahtführung Einrichtungen enthält, die den Filter aus einem Ende des Katheters herausdrücken und in die vorbestimmte Körperstelle in dem Durchgang des Blutgefäßes bringen, dadurch gekennzeichnet, daß der Filter (10) für Blutgerinnsel ein Filter nach einem der vorangehenden Ansprüche ist.

14. Anordnung nach Anspruch 13, die sich ferner durch einen Dilator (60) auszeichnet, der einen Rohrabschnitt (61) mit einem durchgehenden Hohlraum enthält, und daß der Rohrabschnitt einen spitzen Abschnitt (63) mit schmalerem Querschnitt hat, um das Blutgefäß zu erweitern, so daß im Anschluß daran das Einführen des Katheters (40) möglich ist.

15. Anordnung nach Anspruch 14, ferner gekennzeichnet durch:

eine Katheterumhüllung (50), die einen sie durchsetzenden Hohlraum (54) hat, der derart bemessen ist, daß er auf dem rohrförmigen Abschnitt (61) des Dilators (60) aufgenommen ist, wobei der Innenraum der Katheterumhüllung so bemessen ist, daß er den Katheter (40) aufnimmt.

16. Anordnung nach Anspruch 13, dadurch gekennzeichnet, daß die Drahtführung (36) spiralförmig ausgebildet ist und daß die Drückeinrichtung ein gestreckter spiralförmiger Abschnitt (35) der Drahtführung ist, der sich an einem Ende derselben befindet und der relativ zu dem restlichen Teil der Drahtführung gestreckt wird.

Revendications

1. Filtre de caillots de sang (10) pouvant être positionné à l'intérieur du passage fluide d'un vaisseau sanguin dans un corps humain, comprenant:

— un fil métallique à mémoire de forme pouvant être contracté depuis une première position dans laquelle ce fil est pratiquement rectiligne pour permettre l'introduction du filtre à l'intérieur du passage d'un cathéter d'angiographie (40), et dans laquelle le fil emmagasine une énergie potentielle suffisante pour l'amener dans une deuxième position dans laquelle il s'applique en contact sur la paroi interne de ce vaisseau sanguin en une multiplicité de points de contact, aidant ainsi à la fixation du filtre à un emplacement désiré à l'intérieur du vaisseau sanguin et favorisant l'endothélisation et le logement fibreux dans ces points de contact, le fil ayant un diamètre suffisamment faible pour empêcher une occlusion notable de ce vaisseau sanguin lorsque le filtre y est implanté, et

— des moyens de fixation (24, 25) sur le fil pour fixer le filtre à un emplacement déterminé à l'intérieur de ce vaisseau sanguin, ces moyens de fixation comportant une multiplicité de saillies aiguës (27, 30) pénétrant dans la paroi interne de ce vaisseau sanguin,

caractérisé en ce que, dans la deuxième position, le fil est contracté sur sa longueur pour former un treillis métallique ondulé.

2. Filtre de caillots de sang selon la revendication 1, caractérisé par des moyens d'introduction (34) d'une seule pièce avec ce fil pour faciliter l'introduction du fil dans le vaisseau sanguin à travers le passage du cathéter (40).

3. Filtre de caillots de sang selon la revendication 1 et la revendication 2, caractérisé en ce que ces saillies (27, 30) sont disposées aux extrémités opposées du filtre (10).

4. Filtre de caillots de sang selon la revendication 3, caractérisé en ce que les moyens de fixation (24, 25) comportent quatre saillies (27, 30), deux étant chaque fois disposées aux extrémités opposées du filtre, ces saillies étant longitudinalement décalées à chaque extrémité pour faciliter l'introduction du filtre dans le cathéter.

5. Filtre de caillots de sang selon l'une quelconque des revendications précédentes, caractérisé en ce que le filtre comporte une multiplicité de torons (11, 12, 15, 16).

6. Filtre de caillots de sang selon la revendication 5, caractérisé en ce que le filtre comporte quatre torons ou davantage.

7. Filtre de caillots de sang selon la revendication 6, caractérisé en ce que chaque toron (11, 12, 15, 16) est raccordé aux deux extrémités à au moins un autre toron (17, 18) et qu'une multiplicité de ces torons sont raccordés à au moins un point intermédiaire (13, 14) sur leurs longueurs.

8. Filtre de caillots de sang selon la revendication 7, caractérisé en ce que chacune des deux saillies au niveau de l'extrémité avant du filtre comporte une barbe (30) pointue à ses deux extrémités.

9. Filtre de caillots de sang selon la revendication 8, caractérisé en ce que ces barbes (30) ont une longueur inférieure à 1 cm.

10. Filtre de caillots de sang selon la revendication 2, caractérisé en ce que les moyens d'introduction comportent un zigzag (34) dans l'un des torons, ce zigzag procurant une surface pratiquement perpendiculaire à la longueur de ce toron lorsqu'il est dans sa première position, ce qui permet de pousser longitudinalement le filtre (10) dans le passage du cathéter (40) pour son positionnement dans le vaisseau sanguin.

11. Filtre de caillots de sang selon la revendication 9, caractérisé en ce que le fil métallique dont sont constitués les torons est en acier inoxydable trempé.

12. Filtre de caillots de sang selon la revendication 10, caractérisé en ce que ce fil a un diamètre inférieur à 0,38 cm.

13. Ensemble pour effectuer un cathétérisme d'un vaisseau sanguin dans un corps humain afin de filtrer les emboles dans le sang circulant à travers ce vaisseau, cet ensemble comprenant:

— un cathéter (40) dimensionné pour être reçu dans le passage de ce vaisseau sanguin et y être introduit sur un guide-fil (36);

— un filtre de caillots de sang (10); et

— un guide-fil (36) ayant un diamètre dimensionné pour permettre au guide-fil d'être reçu dans le passage du cathéter (40), ce guide-fil comportant des moyens pour repousser le filtre hors d'une extrémité du cathéter et dans un emplacement déterminé à l'intérieur du passage du vaisseau sanguin,

caractérisé en ce que le filtre de caillots de sang (10) est un filtre selon l'une quelconque des revendications précédentes.

14. Ensemble selon la revendication 13, caractérisé par un dilatateur (60) comportant une portion tubulaire (61) ayant un passage traversant, cette portion tubulaire ayant un bout (63) dont la section transversale se rétrécit pour dilater le vaisseau sanguin afin de permettre l'introduction ultérieure du cathéter (40).

15. Ensemble selon la revendication 14, caractérisé par une gaine de cathéter (50) ayant un passage traversant (54) et dimensionnée pour être reçue sur la portion tubulaire (61) du dilatateur (60), le passage de la gaine de cathéter étant dimensionné pour recevoir ce cathéter (40).

16. Ensemble selon la revendication 13, caractérisé en ce que le guide-fil (36) est formé en hélice et que les moyens pour pousser le filtre sont constitués par une portion hélicoïdale étirée (35) de ce guide-fil, située à une extrémité de celui-ci et qui est étirée par rapport à la portion restante du guide-fil.

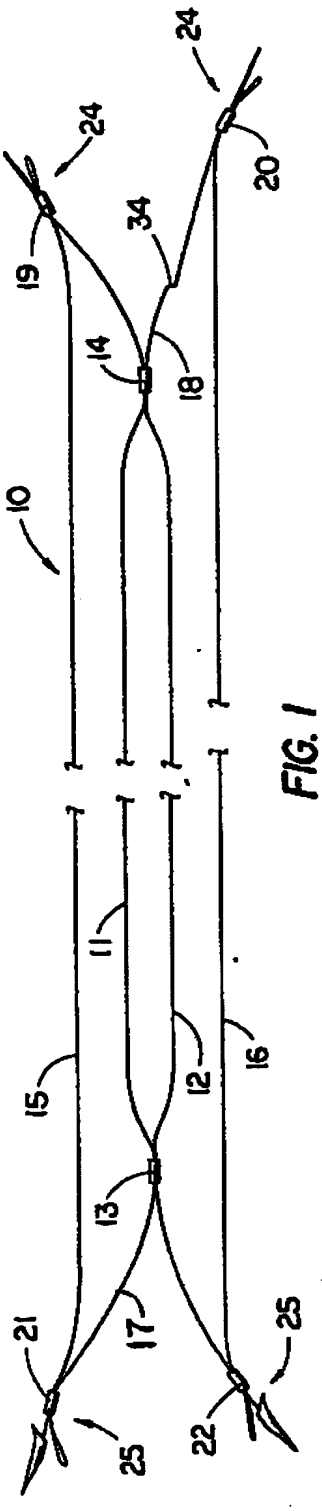

FIG. 1

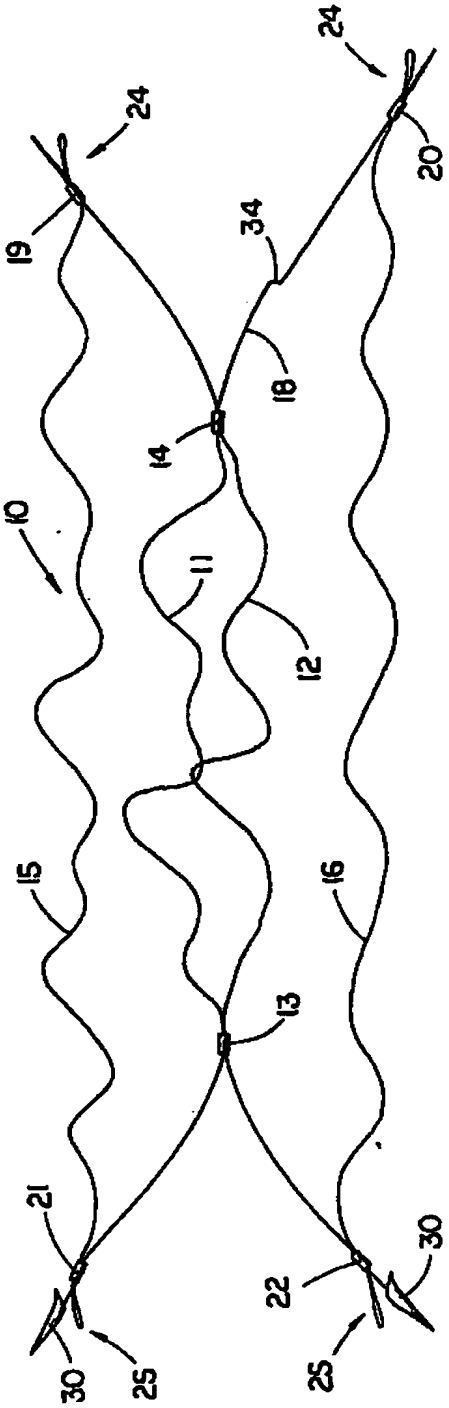

FIG. 2

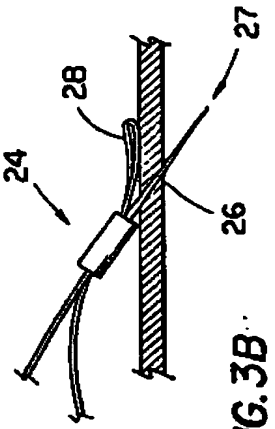

FIG. 3B

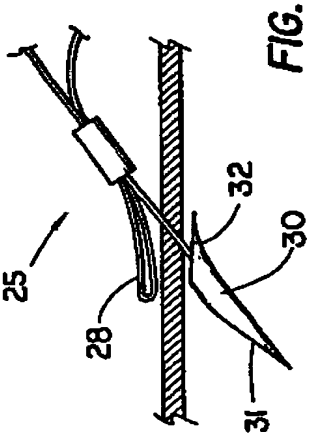

FIG. 3A

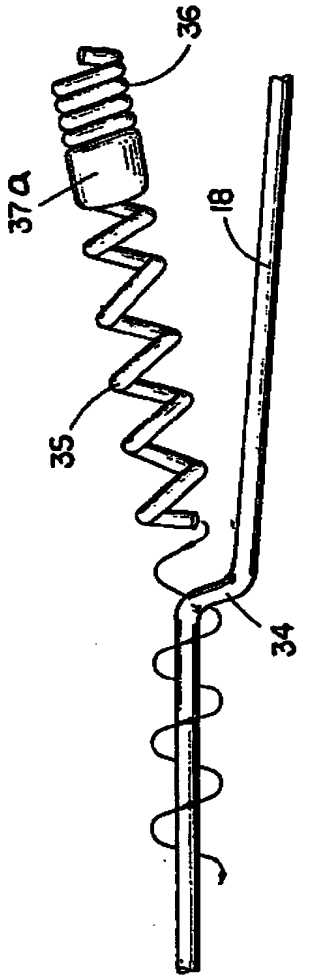

FIG. 4

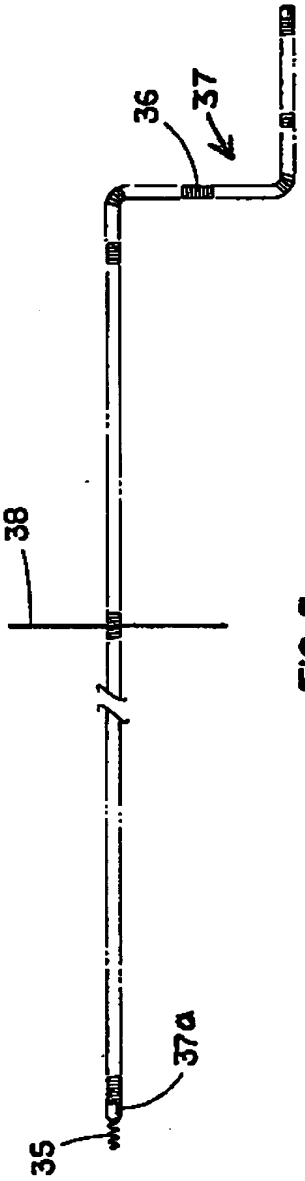

FIG. 5

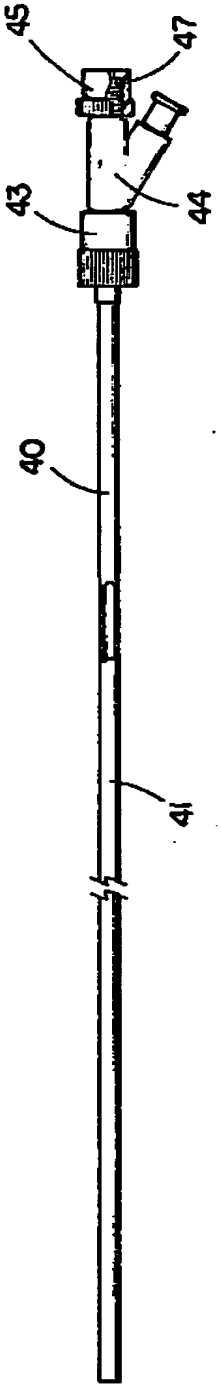

FIG. 6

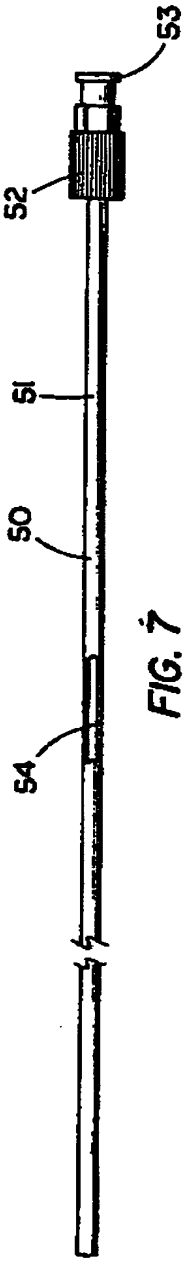

FIG. 7

FIG. 8

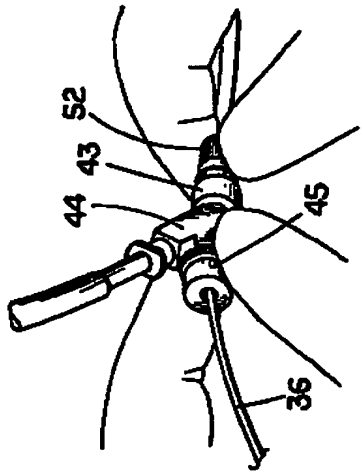

FIG. 10

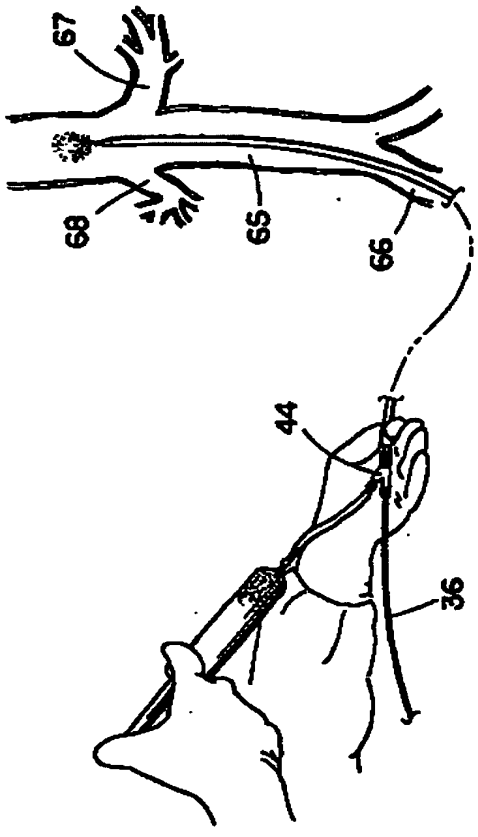

FIG. 9

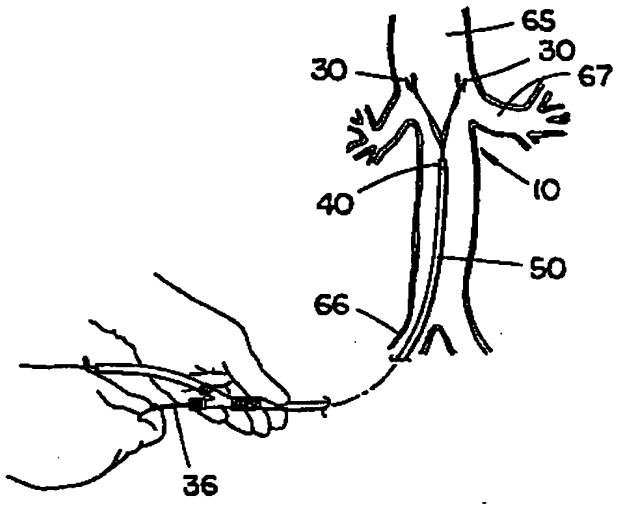

FIG. 11

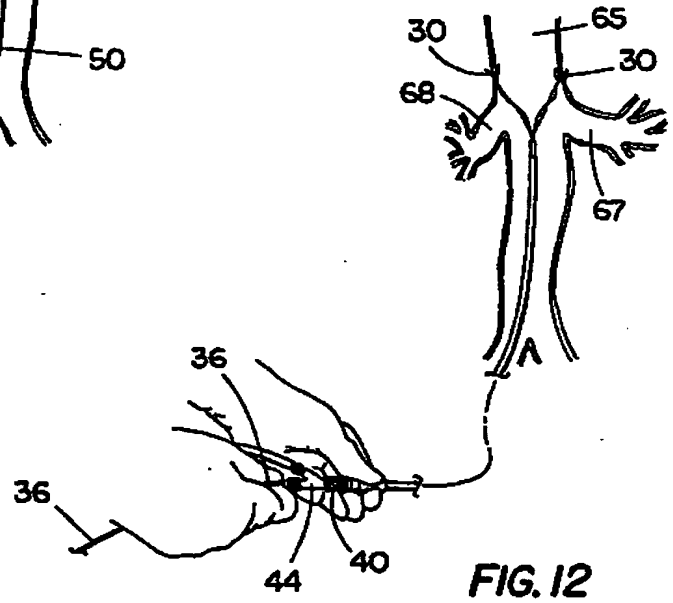

FIG. 12

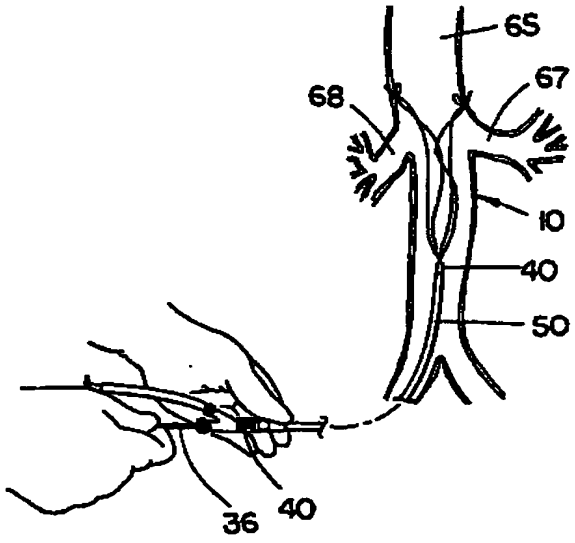

FIG. 13

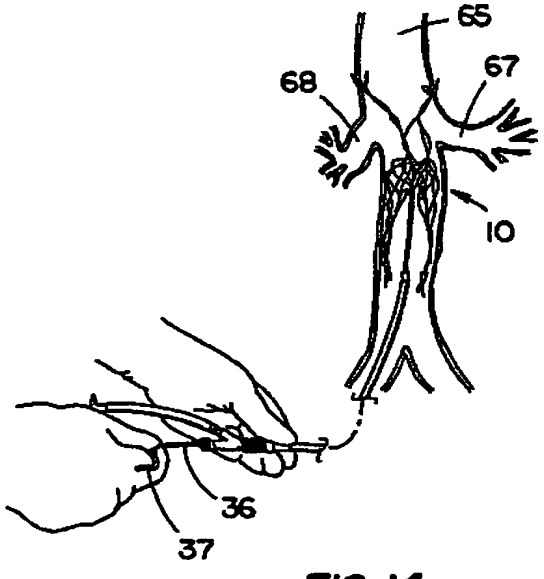

FIG. 14

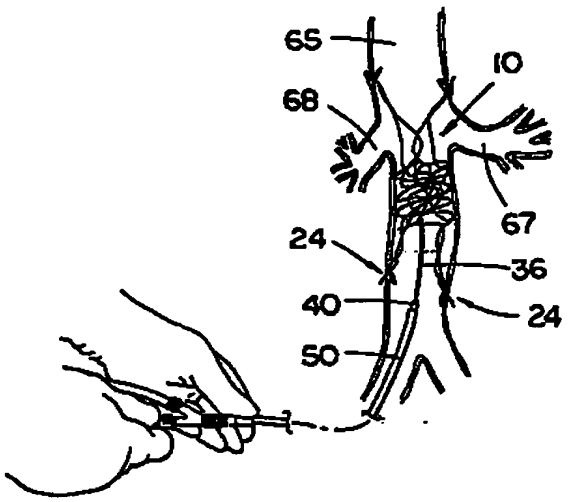

FIG. 15

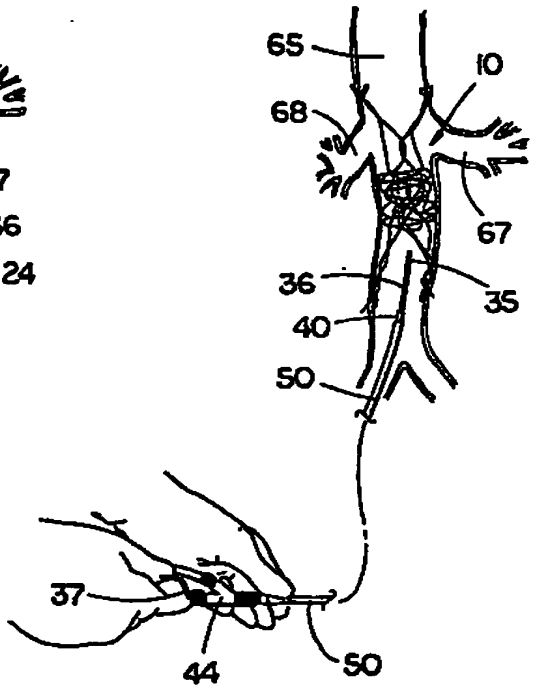

FIG. 16

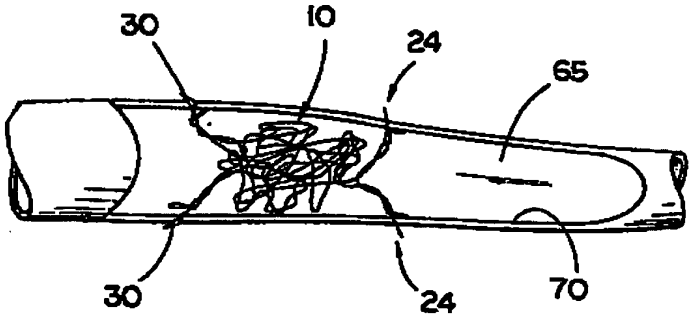

FIG. 17